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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,106	01/23/2002	Lee Harland	PC10970AGLK	9647

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EXAMINER	
SHUKLA, RAM R	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,106	HARLAND, LEE	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-43 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15 and 19-24, drawn to a polynucleotide encoding a GPCR polypeptide, classified in class 536, subclass 23.1.

II. Claims 16-18, drawn to a GPCR polypeptide, classified in class 530, subclass 350.

III. Claim 25, drawn to an antibody against a GPCR polypeptide, classified in class 530, subclass 387.1.

IV. Claim 26, drawn to an agonist of GPCR, classified in class 514, subclass 1.

V. Claims 27, drawn to an antagonist of GPCR, classified in class 514, subclass 1.

VI. Claim 28, drawn to a method of identifying an agonist of GPCR, classified in class 435, subclass 4.

VII. Claims 29, drawn to a method of identifying an antagonist, classified in class 435, subclass 4.

VIII. Claims 30 and 32, drawn to a method of treatment by administering an agonist of GPCR, classified in class 514, subclass 1.

IX. Claim 31 and 34, drawn to a method of treatment by administering an antagonist of GPCR, classified in class 514, subclass 1.

X. Claim 33, drawn to a method of gene therapy by administering a vector expressing an agonist of GPCR, classified in class 514, subclass 44.

XI. Claim 35, drawn to a method of gene therapy by administering a vector expressing an antagonist of GPCR, classified in class 514, subclass 44.

XII. Claim 38 and 40, drawn to a method of protein therapy by administering a GPCR polypeptide, classified in class 514, subclass 2.

XIII. Claim 36 and 37, drawn to a method of antibody therapy by administering a GPCR antibody, classified in class 514, subclass 2.

XIV. Claim 39, drawn to a method of gene therapy by administering a polynucleotide encoding a GPCR polypeptide, classified in class 514, subclass 44.

XV. Claim 41, drawn to an animal genetically engineered to overexpress a GPCR polypeptide, classified in class 514, subclass 44.

XVI. Claim 42, drawn to an animal genetically engineered to underexpress a GPCR polypeptide, classified in class 514, subclass 44.

XVII. Claim 43, drawn to an animal genetically engineered to targeted deletion of a GPCR polypeptide encoding gene, classified in class 514, subclass 44.

3. The inventions of the groups I-V are patentably distinct each from the other because they are drawn to compositions patentably distinct compositions- a nucleic acid, a protein, an antibody, an agonist and an antagonist, that have materially different physical and chemical structures, properties, mode of action and utilities. For example, the physical and chemical characteristics of a nucleic acid are different from those of a protein or an antibody or an agonist or an antagonist. Likewise, the utility of a nucleic acid is different from those of a protein or an antibody or an

agonist or antagonist, for example, a nucleic acid is used for making probes that can be used for northern or southern hybridization, whereas protein can be used for enzyme activity studies while an antibody can be used for western blotting or in-situ hybridization, an agonist may be used for increasing activity of a ligand whereas an antagonist may decreases the activity of a ligand. Additionally, different characteristics of nucleic acids, protein or antibody, agonist or antagonist depend on factors independent of each other. For example, the characteristics of an antibody can vary depending upon the epitope or motif used for raising the antibody and such requirements may not be there for other claimed inventions.

The inventions of the groups VI-XIV are patentably distinct each from the other because they are drawn to methods that have distinct steps unique to a method and use distinct compositions that are not used in other methods. For example, the methods of groups VI and VII are drawn to method of screening for agonists and antagonist, which will have different steps and compositions because the monitoring of an agonist or antagonist to its target will be different. Additionally, methods of screening will be different from those of treatment, groups VIII-XII because they will use different steps, such as administration to a cell or animal. A step used in the method screening can not be used in a method of treatment. The inventions of the groups VIII-XIV are patentably distinct each from the other because they are drawn to method of treating a condition using different compositions that will have different structure, mode of action and function. Additionally, the steps used in one treatment method can not be used in another treatment method. For example, a step of gene therapy can not be used in a method of treatment with an agonist or antibody or antagonist or protein.

The inventions of the groups XV-XVII are patentably distinct each from the other because they are drawn to animals in which a gene is overexpressed, underexpressed or deleted and therefore they will have distinct phenotypes and utilities. For example, an animal overexpressing a gene can be used for screening of compounds that alter its activity while such an assay can not be carried out with an animal that under expresses or does not express the gene.

The inventions of the groups IV, VI & VIII are related as a product, a method of producing a product and a method of using a product. However, these inventions are patentably distinct each from the other because the method of making can produce materially different products with different uses and they may not be used for practicing the same methods. It is noted that the claims do not recite any specific product, rather a genus of unknown structure and properties.

The inventions of the groups V, VII & IX are related as a product, a method of producing a product and a method of using a product. However, these inventions are patentably distinct each from the other because the method of making can produce materially different products with different uses and they may not be used for practicing the same methods. It is noted that the claims do not recite any specific product, rather a genus of unknown structure and properties.

Inventions II and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein of group II can be used in producing antibodies or for treatment or in in vitro activity assay.

Inventions III and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of group III can be used in treatment, in vitro assays, western blotting etc.

Although, the composition of group I may be used in making the animals of groups XV-XVII and practicing the method of group XIV, they are patentably distinct each from the other because the animals so produced and the methods are patentably distinct each other and are multiple utilities for a composition.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and/ or their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

Please note that effective January 13, the offices for Examiner Shukla, SPE Reynolds and LIE William Phillips will move to the new USPTO location in Alexandria, VA and their phone numbers will change. The new phone numbers will be as follows:

Ram Shukla: **(571) 272-0735**

Deborah Reynolds: **(571) 272-0734**

William Phillips: **(571) 272-0548**

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER